

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/666,490	09/19/2003	Jian Li	CEN0312NP	8016

27777 7590 04/05/2006  
PHILIP S. JOHNSON  
JOHNSON & JOHNSON  
ONE JOHNSON & JOHNSON PLAZA  
NEW BRUNSWICK, NJ 08933-7003

EXAMINER

WOODWARD, CHERIE MICHELLE

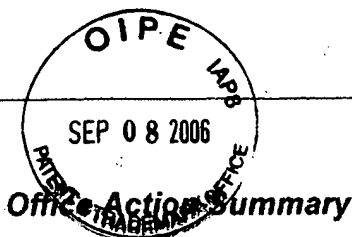
ART UNIT PAPER NUMBER

1647

DATE MAILED: 04/05/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

RECEIVED  
APR 10 2006  
I&J PAT. DKT. SECTION



Application No. 10/666,490	Applicant(s) LI ET AL.	
Examiner Cherie M. Woodward	Art Unit 1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 30 January 2006.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 8-11 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 8-11 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>8/12/2005</u> . | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Formal Matters***

1. Applicants' election without traverse of claims 8-11 in the reply to the Restriction/Election filed on 30 January 2006 is acknowledged. Claims 1-7 and 12-19 have been cancelled by Applicants. Claims 8-11 are under examination.

### ***Information Disclosure Statement***

2. The information disclosure statement (IDS) submitted on 12 August 2005 has been considered. A signed copy is attached hereto.

The reference to the PCT Search Report has been lined through. However, the references contained in the search report are listed on page 1 of the IDS form, individually, and have thus, been considered. The listing of references in the Search Report is not considered to be an information disclosure statement (IDS) complying with 37 CFR 1.98. 37 CFR 1.98(a)(2) requires a legible copy of: (1) each foreign patent; (2) each publication or that portion which caused it to be listed; (3) for each cited pending U.S. application, the application specification including claims, and any drawing of the application, or that portion of the application which caused it to be listed including any claims directed to that portion, unless the cited pending U.S. application is stored in the Image File Wrapper (IFW) system; and (4) all other information, or that portion which caused it to be listed. In addition, each IDS must include a list of all patents, publications, applications, or other information submitted for consideration by the Office (see 37 CFR 1.98(a)(1) and (b)), and MPEP § 609.04(a), subsection I. states, "the list ... must be submitted on a separate paper." Therefore, the references cited in the Search Report have not been considered. Applicant is advised that the date of submission of any item of information or any missing element(s) will be the date of submission for purposes of determining compliance with the requirements based on the time of filing the IDS, including all "statement" requirements of 37 CFR 1.97(e). See MPEP § 609.05(a).

### ***Specification***

3. The disclosure is objected to because of the following informalities:
  - a. There are a series of blank lines on page 5, lines 14-16.
  - b. An extra "0" is listed in the phrase "95%-1000%" on p. 14, line 13.

Art Unit: 1647

c. TNF- $\alpha$ , page 30, line 35.

d. There is no web-based reference affiliated with "copewithcytokines.com" (see specification, p. 31, line 5). If the reference is intended to be directed to www.copewithcytokines.de, then the phrase should be corrected to recite the correct web-based reference.

Appropriate correction is required.

4. The use of the trademarks, such as NASBA (page 7, line 28), NEUPOGEN (p. 17, line 9, p. 28, line 5, p. 31), EPOETIN ALPHA (p. 17, line 9, p. 28, line 4, p. 31), LEUKINE (p. 17, line 9, p. 28, line 5, p. 31), numerous trade names on page 22, lines 23-31, including HUMATROPEN (p. 22, line 31), multiple inhalers and nebulizers listed on page 35, have been noted in this application. They should be capitalized wherever they appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

5. The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicants' cooperation is requested in correcting any errors of which Applicants may become aware in the specification.

6. The attempt to incorporate subject matter into this application by reference to GenBank Accession numbers and laboratory names of proteins is ineffective because protein and nucleic acid sequences that are an essential part of the invention must be disclosed by sequence. As such, the incorporation by reference to GenBank Accession Numbers and references to proteins by their laboratory names are not in compliance with 37 CFR 1.57. Applicant may overcome the rejection by amending the specification in accordance with 37 CFR 1.57(g). However, no new matter may be introduced.

7. The disclosure is objected to under 37 CFR 1.821(d) because a SEQ ID NO is required for any disclosed peptide with four or more amino acids. No SEQ ID NOs have been provided for the amino acid sequences in excess of four amino acids referenced in the disclosure (see i.e. p. 45).

Art Unit: 1647

***Claim Rejections - 35 USC § 112, Second Paragraph***

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claim 9 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is not clear from the claim, as written, whether the "further" is part of the recited method or whether what follows is a new method. A remedial suggestion to the claim language would be "A dendritic cell preparation produced by the method of claim 8 further comprising contacting...."

***Claim Rejections - 35 USC § 102***

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

11. Claims 8-11 are rejected under 35 U.S.C. 102(b) as being anticipated by Lardon et al., (Immunology 1997 Aug;91(4):553-9).

The claims recite a preparation of dendritic cells having at least two cell surface markers selected from the group consisting of CD1a, HLA-DR, and CD86, produced by contacting hematopoietic stem or progenitor cells with IL-18. A dendritic cell preparation according to claim 8, produced further by contacting the hematopoietic stem or progenitor cells with a molecule selected from the group consisting of flt-3-ligand, GM-CSF-IL-4, TNF- $\alpha$ , IL-3, c-kit ligand, and fusions of GM-CSF and IL-13. An antigen expressing dendritic cell population produced by the recited process, wherein step a of the process further comprises contacting the hematopoietic stem cell or progenitor cells with a molecule selected from the group consisting of GM-CSF, IL-4, TNF- $\alpha$ , IL-3, c-kit ligand, and fusions of GM-CSF and IL-3.

Lardon et al., teach the generation of dendritic cells from bone marrow progenitors. Phenotypic analysis of dendritic cells with cell surface markers HLA-DR, CD1a, and CD86 are taught at p. 555. The claimed preparations of dendritic cells and antigen-expressing dendritic cells are well known in the art

Art Unit: 1647

(see, i.e. Lardon et al., *supra*). “[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process.” In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985) (citations omitted).

12. Claims 8-11 are rejected under 35 U.S.C. 102(e) as being anticipated by Zitvogel et al., US Patent 6,849,452 (1 February 2005, priority to 2 March 1999) (hereinafter the ‘452 patent).

The claims recite a preparation of dendritic cells having at least two cell surface markers selected from the group consisting of CD1a, HLA-DR, and CD86, produced by contacting hematopoietic stem or progenitor cells with IL-18. A dendritic cell preparation according to claim 8, produced further by contacting the hematopoietic stem or progenitor cells with a molecule selected from the group consisting of flt-3-ligand, GM-CSF-IL-4, TNF-a, IL-3, c-kit ligand, and fusions of GM-CSF and IL-13. An antigen expressing dendritic cell population produced by the recited process, wherein step a of the process further comprises contacting the hematopoietic stem cell or progenitor cells with a molecule selected from the group consisting of GM-CSF, IL-4, TNF-a, IL-3, c-kit ligand, and fusions of GM-CSF and IL-3.

The ‘452 patent teaches a preparation of dendritic cells, compositions containing them, and uses thereof (column 2, lines 52-55). The ‘452 patent also teaches a the use of dendritic cells to prepare a composition intended to activate natural killer (NK) cells *in vivo* (column 2, lines 40-43), including culturing the cells in the presence of IL-18 (column 1, lines 61-63). The bone-marrow derived dendritic cells (column 7, lines 30-31) expressing HLA-DR, CD40, CD80, CD86, CD83, and CD1a are taught at column 6, lines 16-18. The dendritic cells treated with GM-CSF and Flt3L are taught at column 12, lines 9-25. IL-4 is taught at column 4, lines 30-31, and GM-CSF plus IL-13 is taught at column 14, lines 9 and 27. Antigen-stimulated dendritic cells and numerous methods of producing them are taught at column 14, lines 60-67 to column 15, lines 1-67 to column 16, lines 1-18. Specifically, antigen-pulsing is taught at column 15, lines 19-31 and transfecting dendritic cells with a gene encoding an antigenic-specific peptide is taught at column 16, lines 1-18.

**NO CLAIM IS ALLOWED.**

Art Unit: 1647

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cherie M. Woodward whose telephone number is (571) 272-3329. The examiner can normally be reached on Monday - Thursday 9:00am-7:30pm (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached on (571) 272-0961. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

CMW

*Brenda Brumback*  
BRENDA BRUMBACK  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600



PTO/SB/08A (08-00)  
Approved for use through 10/31/2002. OMB 0851-0031  
U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

Substitute for form 1449A/PTO		<b>Application Number</b>	10/686,490
<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b> (see as many sheets as necessary) Sheet 1 of 1		<b>Filing Date</b>	September 19, 2003
		<b>First Named Inventor</b>	Jian Li, et al.
		<b>Group Art Unit</b>	1648
		<b>Examiner Name</b>	Jiang, Dong
		<b>Attorney Docket Number</b>	CEN-312

#### U.S. PATENT DOCUMENTS

Examiner Initials	Cite No. <sup>1</sup>	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document mm-dd-yyyy	Pages, Columns, Lines, where relevant passages or relevant figures appear
		Number	Kind Code <sup>2</sup> (if known)			
CMW		6,790,440		Hellstrand, et al.	09-14-2004	

#### FOREIGN PATENT DOCUMENTS

Examiner Initials	Cite No. <sup>1</sup>	Foreign Patent Document			Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document mm-dd-yyyy	Pages, Columns, Lines, where relevant passages or relevant figures appear	T <sup>3</sup>
		Office <sup>4</sup>	Number <sup>4</sup>	Kind Code <sup>5</sup>				
Examiner Signature						Date Considered		

**EXAMINER:** Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Unique citation designation number. <sup>2</sup> See attached Kinds of U.S. Patent Documents. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup> Applicant is to place a check mark here if English language Translation is attached.

**Burden Hour Statement:** This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U. S. Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS, SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450  
PTO/SB/08A (08-00)

Approved for use through 10/31/2002. OMB 0851-0031  
U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

Substitute for form 1448A/PTO		<b>Application Number</b>	10/686,490
<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b> (see as many sheets as necessary)		<b>Filing Date</b>	September 19, 2003
		<b>First Named Inventor</b>	Jian Li, et al.
		<b>Group Art Unit</b>	1648
		<b>Examiner Name</b>	Jiang, Dong
		<b>Attorney Docket Number</b>	CEN-312

OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS			
Examiner's Initials <sup>1</sup>	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	T <sup>2</sup>
CMW		PARAJULI, P. et al. "Flt3 Ligand and Granulocyte-Macrophage Colony-Stimulating Factor Preferentially Expand and Stimulate Different Dendritic and T-Cell Subsets". Exp. Hematol. October, 2001, Vol. 29, No. 10, pp. 1185-1193.	
Examiner Signature			Date Considered
			3/20/2006

**EXAMINER:** Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Unique citation designation number. <sup>2</sup> Applicant is to place a check mark here if English language Translation is attached.

**Burden Hour Statement:** This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U. S. Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.



<b>Application Number</b>	10/666,490
<b>Filing Date</b>	September 19, 2003
<b>First Named Inventor</b>	Jian Li, et al.
<b>Group Art Unit</b>	1846
<b>Examiner Name</b>	Jiang, Dong
<b>Attorney Docket Number</b>	CEN-312

<b>Notice of References Cited</b>	Application/Control No. 10/666,490		Applicant(s)/Patent Under Reexamination LI ET AL.	
	Examiner Cherie M. Woodward		Art Unit 1647	Page 1 of 1

**U.S. PATENT DOCUMENTS**

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	Classification
*	A	US-6,849,452	02-2005	Zitvogel et al.	435/347
	B	US-			
	C	US-			
	D	US-			
	E	US-			
	F	US-			
	G	US-			
	H	US-			
	I	US-			
	J	US-			
	K	US-			
	L	US-			
	M	US-			

**FOREIGN PATENT DOCUMENTS**

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Country	Name	Classification
	N					
	O					
	P					
	Q					
	R					
	S					
	T					

**NON-PATENT DOCUMENTS**

*		Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages)
	U	Lardon et al., Immunology 1997 Aug;91(4):553-9
	V	
	W	
	X	

\*A copy of this reference is not being furnished with this Office action. (See MPEP § 707.05(a).)  
Dates in MM-YYYY format are publication dates. Classifications may be US or foreign.